DETAILED ACTION

The preliminary amendment filed 09 January 2006 has been entered. Claims 1-46 have been canceled and claims 47-65 have been added.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 47-49, drawn to nucleic acids.

Group II, claim(s) 50-53, drawn to proteins.

Group III, claim(s) 54, drawn to a method of increasing expression of a nucleic acid.

Group IV, claim(s) 54, drawn to a method of decreasing expression of a nucleic acid.
Group V, claim(s) 55, drawn to a method of increasing the activity of a protein.

Group VI, claim(s) 55, drawn to a method of decreasing the activity of a protein.

Group VII, claim(s) 56, 58, drawn to a method of treating with an agent that increases the expression of a nucleic acid.

Group VIII, claim(s) 56, 58, drawn to a method of treating with an agent that decreases the expression of a nucleic acid.

Group IX, claim(s) 56, 59, drawn to a method of treating with an agent that increases the activity of a protein.

Group X, claim(s) 56, 59, drawn to a method of treating with an agent that decreases the activity of a protein.

Group XI, claim(s) 57 and 60, drawn to a method of treatment by administration of a nucleic acid.

Group XII, claim(s) 61, drawn to a modulator of expression which increases expression.

Group XIII, claim(s) 61, drawn to a modulator of expression which decreases expression.

Group XIV, claim(s) 62-65, drawn to a method of detecting disease by determining expression of a gene.

Group XV, claim(s) 62-65, drawn to a method of detecting disease by determining the activity of a protein.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature defines a contribution over the prior art. The special technical feature of Group I is known in the art since the invention of Group I encompasses any nucleic acid molecule that encodes a molecule or derivative or homolog associated with diabetes, obesity, metabolic disorder, etc. wherein the nucleic acid is capable of hybridizing to a given sequence. Since no conditions are provided, all nucleic acids would hybridize given the proper conditions, all of which are encompassed by the currently drafted claims. Based on the claims, nucleic acids encoding such molecules as insulin or leptin would be encompassed by the claims, which are known in the art at the time of the instant application. Therefore, this cannot serve as a basis for unity of invention because it does not define a contribution over the prior art.

The inventions of Groups I-II and XII-XIII lack a corresponding special technical feature because each invention is directed to a distinct molecule, having a different structure and different function. The inventions of Groups III-XI and XIV-XV are directed to various methods. 37 CFR 1.475 does not provide for the inclusion of multiple inventions. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims will be considered the main invention (see PCT Article 17(3)(a). Accordingly, the inventions of Groups III-XI and XIV-XV do not have unity of invention with the compositions of Groups I-II and XII-XIII.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

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